



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS AND PATENT INTERFERENCES

Attorney Docket No. 054707-0337

In re patent application of
Gregory S. Hamilton et al.

Serial No. 09/204,238

Group Art Unit: 1625

Filed: December 3, 1998

Examiner: Celia C. Chang

For: MULTIPLE HETEROATOM
CONTAINING HETEROCYCLIC RING
COMPOUNDS SUBSTITUTED WITH
CARBOXYLIC ACIDS AND ISOTERES
THEREOF

BRIEF ON APPEAL

Commissioner for Patents
Washington, DC 20231

Sir:

This Appeal Brief is being filed in triplicate together with a check in the amount of \$160.00 covering the fee under 37 C.F.R. § 1.17(c) for a small entity. If this fee is deemed to be insufficient, authorization is hereby given to charge any deficiency (or to credit any overpayment) to the undersigned's Deposit Account No. 19-0741.

This is an appeal from the decision dated March 1, 2002 ("the final Office Action"), finally rejecting claims 73-86.

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REAL PARTY IN INTEREST

The real party in interest in this case is the assignee of record, GPI NIL Holdings, Inc.

RELATED APPEALS AND INTERFERENCES

Appellants, Appellants' Representative, and the assignee of record are not aware of any other appeals or interferences that would directly affect, be directly affected by, or have a bearing on the Board's decision in this appeal.

STATUS OF CLAIMS

Claims 73-86 are pending. Claim 73-86 stand provisionally rejected for non-statutory double patenting over U.S. Patent Application No. 09/159,105. In the Advisory Action (see paragraph no. 5) the Examiner has apparently withdrawn all other grounds of rejection in the final Office Action. Applicants appeal the final rejection of claims 73-86.

STATUS OF AMENDMENTS

The Examiner has entered the amendment under 37 C.F.R. § 1.116 filed on July 1, 2002, as stated in the Advisory Action dated July 18, 2002 ("the Advisory Action") (paragraph no. 7).

SUMMARY OF INVENTION

A method of treating a neurological disorder in an animal, comprising administering to the animal an effective amount of a compound to stimulate growth of damaged peripheral nerves or to promote neuronal regeneration, where the compound has the formula (I).

ISSUES

There is one issue on appeal: Whether claims 73-86 are unpatentable for non-statutory double patenting over U.S. Patent Application No. 09/159,105?

GROUPING OF CLAIMS

The claims stand or fall together.

ARGUMENT

I. The Rejection of Claims 73-86 for Non-Statutory Double Patenting

Claims 73-86 stand provisionally rejected for non-statutory double patenting over claims 1-177 of U.S. Patent Application No., 09/159,105 ("the '105 application") in view of MedLine 98242495 ("Feghali").

The Office has maintained this rejection "for the reasons of record" (final Office Action, page 2, paragraph #2). The non-final Office Action dated 19-Sep-01 ("the non-final Action") asserted that claims 1-177 of the '105 application recite treating a disorder generically embraced by the present claims and that the disclosed compounds encompass those recited in the present claims (non-final Office Action, page 2, paragraph no. 2).

According to the M.P.E.P., a provisional double patenting rejection may be due between "two copending applications filed by the same inventive entity, or by different inventive entities having a common inventor, and/or by a common assignee." M.P.E.P. § 804.I.B., page 800-19 (8th Ed. August 2001). "[A]ny analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. § 103 obviousness determination." M.P.E.P. § 804.II.B.1, citing *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991) and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). "The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness." M.P.E.P. § 2144.08.II, citing *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994).

The Examiner has based the obviousness conclusion exclusively on the genus-species relationship between the claims of the '105 application and the present claims. In doing so, the

Examiner has applied a *per se* rule in clear violation of the relevant USPTO guidelines and case law. The Examiner should therefore be reversed.

Factual findings that are material to patentability must be supported by substantial evidence. *In re Zurko*, 258 F.3d 1379, 1386 (Fed. Cir. 2001).

The Examiner has not provided substantial evidence that the '105 application is an application "filed by the same inventive entity, or by different inventive entities having a common inventor, and/or by a common assignee." The present application is assigned to "GPI NIL Holdings, Inc." which is entirely owned by Guilford Pharmaceuticals Inc. The Examiner has referred to an international application (WO 00/16603) listing as applicants Amgen, Inc. and Guilford Pharmaceuticals Inc. and claiming priority to the '105 application. However, the Examiner has not provided evidence that the '105 application was then or is currently assigned to GPI NIL Holdings, Inc. or to any company related to Guilford Pharmaceuticals Inc. Applicants have been unable to obtain a copy of the '105 application. However, WO 99/14998 (of record in this case in Form PTO-892 of Paper No. 17) also claims priority to the '105 application. WO 99/14998 has no common inventors with the '105 application.

Because there is no substantial evidence of either common ownership or a common inventor, the Board should reverse the Examiner on this issue.

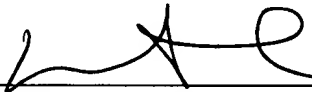
CONCLUSION

Based upon the foregoing, Appellants respectfully submit that the provisional rejection is improper. Accordingly, the Board is respectfully requested to reverse the rejection.

Please charge or credit all fees as needed to Deposit Account No. 19-0741.

Respectfully submitted,

1-OCT-2002
Date

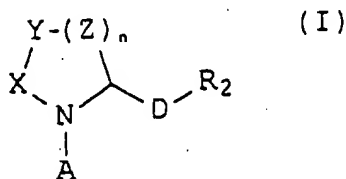

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Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.

APPENDIX (Claims On Appeal)

73. A method of treating a neurological disorder in an animal, comprising:
administering to the animal an effective amount of a compound to stimulate growth of
damaged peripheral nerves or to promote neuronal regeneration, where the compound has the
formula (I):

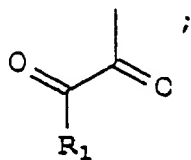


where

X, Y, and Z are independently selected from the group consisting of C, O, S, or N, provided that
X, Y, and Z are not all C;

n is 1;

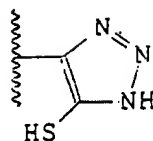
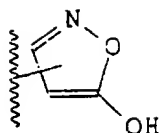
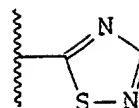
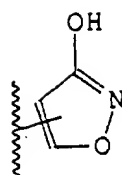
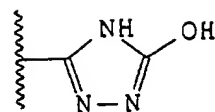
A is



R₁ is selected from the group consisting of hydrogen, C₁-C₉ straight or branched chain
alkyl, C₂-C₉ straight or branched chain alkenyl, aryl, heteroaryl, carbocycle, and heterocycle;

D is selected from the group consisting of a bond, C₁-C₁₀ straight or branched chain
alkylene, ethylene (-CH=CH-), and butylene;

R₂ is a carboxylic acid or a carboxylic acid isostere selected from the group consisting of:



wherein said alkyl, alkenyl, alkylene, ethylene, butylene, aryl, heteroaryl, carbocycle, heterocycle, or carboxylic acid isostere is optionally substituted with one or more substituents selected from R_3 , where

R_3 is selected from the group consisting of hydrogen, hydroxy, halo, haloalkyl, thiocarbonyl, alkoxy, alkenoxy, alkylaryloxy, aryloxy, arylalkyloxy, cyano, nitro, imino, alkylamino, aminoalkyl, sulfhydryl, thioalkyl, alkylthio, sulfonyl, C_1 - C_6 straight or branched chain alkyl, C_2 - C_6 straight or branched chain alkenyl or alkynyl, aryl, heteroaryl, carbocycle, heterocycle, and CO_2R_4 where R_4 is selected from the group consisting of hydrogen, C_1 - C_9 straight or branched chain alkyl, and C_2 - C_9 straight or branched chain alkenyl; or a pharmaceutically acceptable salt, or solvate thereof.

74. The method of claim 73, wherein the neurological disorder is selected from the group consisting of peripheral neuropathies caused by physical injury or disease state, physical damage to the brain, physical damage to the spinal cord, stroke associated with brain damage, and neurological disorders relating to neurodegeneration.

75. The method of claim 73, wherein the neurological disorder is selected from the group consisting of Alzheimer's Disease, Parkinson's Disease, and amyotrophic lateral sclerosis.

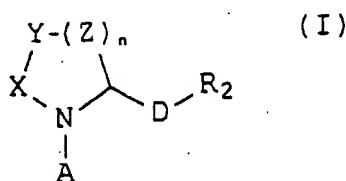
76. The method of claim 73, wherein the neurological disorder is Alzheimer's disease.

77. The method of claim 73, wherein the neurological disorder is amyotrophic lateral sclerosis.

78. The method of claim 73, wherein said compound is non-immunosuppressive.

79. The method of claim 73, wherein Y is O, S, or N; R₁ is C₁-C₉ straight or branched chain alkyl or aryl; and D is a bond or CH₂.

80. A method of treating a neurological disorder in an animal, comprising:
administering to the animal an effective amount of a compound to stimulate growth of damaged peripheral nerves or to promote neuronal regeneration, wherein the compound has the formula (I):

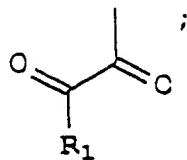


where

X, Y, and Z are independently selected from the group consisting of C, O, S, or N, provided that X, Y, and Z are not all C;

n is 1;

A is



R₁ is selected from the group consisting of hydrogen, C₁-C₉ straight or branched chain alkyl, C₂-C₉ straight or branched chain alkenyl, aryl, heteroaryl, carbocycle, and heterocycle;

D is selected from the group consisting of a bond, C₁-C₁₀ straight or branched chain alkylene, ethylene (-CH=CH-), and butylene;

R₂ is a carboxylic acid or carboxylic acid isostere selected from the group consisting of: -COOH, -SO₃H, -SO₂HNR₃, -PO₂H, -CN, -PO(OH)(OR₃), -C(O)NHOH, -C(O)NHSO₂R₃, and -CONHCN;

wherein said alkyl, alkenyl, alkylene, ethylene, butylene, aryl, heteroaryl, carbocycle, heterocycle, or carboxylic acid isostere is optionally substituted with one or more substituents selected from R₃, where

R₃ is selected from the group consisting of hydrogen, hydroxy, halo, haloalkyl, thiocarbonyl, alkoxy, alkenoxy, alkylaryloxy, aryloxy, arylalkyloxy, cyano, nitro, imino, alkylamino, aminoalkyl, sulfhydryl, thioalkyl, alkylthio, sulfonyl, C₁-C₆ or branched chain alkyl, C₂-C₆ straight or branched chain alkenyl or alkynyl, aryl, heteroaryl, carbocycle, heterocycle, and CO₂R₄ where R₄ is selected from the group consisting of hydrogen, C₁-C₉ straight or branched chain alkyl, and C₂-C₉ straight or branched chain alkenyl; or a pharmaceutically acceptable salt, or solvate thereof.

81. The method of claim 80, wherein the neurological disorder is selected from the group consisting of peripheral neuropathies caused by physical injury or disease state, physical damage to the brain, physical damage to the spinal cord, stroke associated with brain damage, and neurological disorders relating to neurodegeneration.

82. The method of claim 80, wherein the neurological disorder is selected from the group consisting of Alzheimer's Disease, Parkinson's Disease, and amyotrophic lateral sclerosis.

83. The method of claim 80, wherein the neurological disorder is Alzheimer's Disease.

84. The method of claim 80, wherein the neurological disorder is amyotrophic lateral sclerosis.

85. The method of claim 80, wherein said compound is non-immunosuppressive.

86. The method of claim 80, wherein the compound is selected from the group consisting of:

